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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 08/963,239 | 11/03/1997 | EDWARD J. GOUGH | 13724-787 | 9828 |

22918 7590 03/23/2004

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| EXAMINER |
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PEFFLEY, MICHAEL F

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| ART UNIT | PAPER NUMBER |
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3739

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DATE MAILED: 03/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/963,239

Applicant(s)

GOUGH ET AL.

Examiner

Michael Peffley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 53-62 and 64-73 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 53-62 and 64-73 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 21, 2003 has been entered.

Oath/Declaration

It is noted that applicant's petition under 37 CFR 1.47(a) has been dismissed. Currently, there is no accurate oath/declaration in the file which is properly executed. Correction and clarification is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 53-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stadelmayr (DE 2,124,684) in view of the teaching of Edwards et al ('675).

Stadelmayr provides a device which includes an elongate delivery device (1) having a tissue piercing distal end (4) and a plurality of electrodes that are precurved, or "loaded", to extend from the elongate delivery device with curvature (see Figure 3 and page 3 of the translation). Stadelmayr specifically states that the device may be

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used to introduce electrodes into tumors to destroy the tumorous tissue (page 3 of the translation). There is no specific disclosure that the electrodes are RF ablation electrodes, nor of the use of sensors to monitor conditions and control the delivery of RF energy to the tumorous tissue.

Edwards et al ('675) also disclose a device for the ablation of tumors. The device includes an elongate member and a plurality of electrodes deployed from the elongate member just as in Stadelmayr. In particular, Edwards et al specifically teach that it is known to use RF electrodes for the ablation and destruction of tumors, and further teach of providing various sensors for monitoring temperature and impedance to affect feedback control to the RF generator such that the delivery of energy is controlled based on the sensed parameters.

To have provided the Stadelmayr device with an RF energy source and feedback mechanism to effectively destroy tumor tissue would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Edwards et al.

Claims 57-62 and 64-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al ('675) in view of the teaching of Stadelmayr (DE 2,124,684).

The Edwards et al device has been addressed previously. In particular, Edwards et al disclose a device which includes an elongate delivery member and a plurality of RF electrodes deployable therefrom. Edwards et al disclose the various types of insulation, sensors, infusion mediums and feedback control as set forth in applicant's claims.

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Edwards et al also disclose the specific steps of inserting the electrodes into tissue to ablate tumorous tissue. However, Edwards et al fail to specifically teach that the electrodes are pre-shaped to assume a curved configuration when deployed from the elongate member. Rather, Edwards et al provide guides within the elongate member for controlling the deployment shape of the electrodes.

Stadelmayr, as addressed previously, also discloses a device for destroying tumors. The Stadelmayr device also includes an elongate delivery member and a plurality of electrodes deployed from the delivery member. In particular, Stadelmayr specifically teach that the electrodes may be pre-shaped, or "loaded", to assume the desired umbrella shape upon deployment. The use of pre-formed wires to assume the desired shape, in lieu of the guides used by Edwards et al to assume the same shape, is deemed an obvious alternative to one of ordinary skill in the art.

To have provided the Edwards et al device with pre-formed wires to assume a desired shape upon deployment is deemed to be an obvious modification for one of ordinary skill in the art, particularly in view of the teaching of Stadelmayr.

Response to Arguments

Applicant's arguments with respect to the pending claims have been considered but are moot in view of the new ground(s) of rejection.

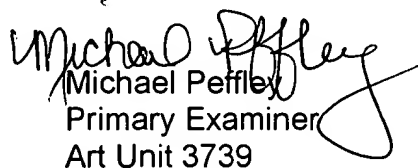
It is noted that applicant has filed an acceptable terminal disclaimer and has obviated the double patenting issues.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (703) 308-4305. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (703) 308-0994. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Michael Peffley
Primary Examiner
Art Unit 3739

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March 18, 2004